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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GOLDBERG, JEANINE ANNE	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 04/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/039,288	BASTIAN, BORIS C.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Objections

1. Claim 9 is objected to because of the following informalities. Claim 9 appears to contain a mis-spelling of probe. The claim recites "eprobe." Appropriate correction is required.

Claim Rejections - 35 USC § 112- Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for typing a skin tumor sample as a congental melanocytic nevus by detecting the loss of complete chromosome 7, does not reasonably provide enablement for detecting partial chromosome loss or gain and detecting a gain of chromosome 10 or 11. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The claims are broadly drawn to a method of typing a growth arising in association with a congenital melanocytic nevus by analyzing chromosomal changes selected from the group consisting of gain of chromosome 10, gain of chromosome 11, a loss of chromosome 7 or a combination thereof, thereby typing the skin tumor sample as a benign growth.

The art teaches chromosomal analysis for Spitz nevi, melanoma, superficial spreading melanoma (SSM) and acral lentiginous melanoma (AM). Bastian et al (US Pat. 6,261,775, July 17, 2001) teaches CGH analysis of primary cutaneous melanomas and Spitz nevi (Figures 1 and 2). As seen in Figure 1, primary cutaneous melanoms lact a loss of chromosome 7, a gain in chromosome 10 and have partial gains in chromosome 11. As seen in Spitz nevi (Figure 2), partial chromosomal gains are seen in chromosome 11.

Bastian (US Pat. 6,465,180, October 15, 2002) illustrates chromosomal localizations of DNA sequence copy number changes in AM and SSMs detected by CGH. As seen in Figure 1, chromosome 7 is not lost, chromosome 10 is not gained, however chromosome 11 contains gains in partial regions.

Thompson et al (Cancer Genet. Cytogenet. Vol. 83, pages 93-104 1995) teaches the analysis of melanoma. As seen in Figure 2, the chromosome profiles from

49 cases were analyzed. It is apparent that melanoma contains partial losses in chromosome 7 are present, partial gains in chromosome 10 and 11 are present.

The specification teaches performing comparative genomic hybridization on congenital melanocytic nevus. Table 2 teaches the frequency of observed changes. Based upon the Table, the following changes were observed

	CMN from Table 2	Primary cutaneous melanoma from Table 3
Gain of Chromosome 10	1/10	
Gain of Chromosome 11	1/10	
Loss of Chromosome 7	3/10	0/122

Neither the art nor the specification teaches how to use the claimed invention as broadly as claimed. First the claims appear to be broadly drawn to a gain of chromosome 10, gain of chromosome 11 or a loss of chromosome 7, not limited to a gain of the whole chromosome 10 or 11 or a loss of the whole chromosome 7. As noted below it is unclear whether the claim is directed to whole chromosome losses/gains only or whether the claim encompasses partial chromosome losses/gains. Since the claim also encompasses "a combination thereof" the claim appears to be encompassing partial chromosome gains/losses. It is apparent from the art that partial gains in chromosome 10 and 11 and partial losses in chromosome 7 are found in melanoma, as exemplified by Bastian and Thompson. Therefore, based upon the

teachings in the art, the skilled artisan would be unable to distinguish between congenital melanocytic nevus and melanoma based on the detection of a change in chromosome 7, 10 and 11. The specification has not taught the skilled artisan how to type a growth arising in association with a congenital melanocytic nevus since the gains and losses are seen in both congenital melanocytic nevus and melanoma. Therefore, the skilled artisan would be required to perform undue experimentation to be able to distinguish between a partial gain of chromosomes 10 and 11 and a partial loss of chromosome 7 as indicative of congenital melanocytic nevus.

Further, the data in the specification teaches that the gain of chromosome 10 and 11 in a single CMN sample. The specification fails to provide any examples indicating that merely a gain in chromosome 10 or merely a gain in chromosome 11 has been found in any CMN. Moreover, the presence of a single sample is not a trend. No reasonable artisan would infer a method of typing a growth as a CMN by the detection in a single sample. The specification does not indicate that the finding of this single sample demonstrates that the association between the gain in chromosomes 10 and 11 and congenital melanocytic nevus. A representative number of samples were not analyzed which showed a correlation between gain of chromosome 10 or 11 and the occurrence in CMN. The specification does not provide any statistical analysis that demonstrates that this isolated occurrence is a reliable means for typing a growth arising in association with a congenital melanocytic nevus. Therefore, the skilled artisan would be required to perform additional undue experimentation to determine whether this chromosomal change is in fact associated with congenital melanocytic nevus or

whether this chromosomal change is merely an outlier and an anomaly. Moreover, based upon the data presented in the specification it is unpredictable that a detection of a gain of chromosome 10 or gain of chromosome 11 alone is predictably associated with congenital melanocytic nevus. The specification only demonstrates a congenital melanocytic nevus which contains both of these gains in additional gains in chromosomes 16, 20 and 22. Since the underlying principles of congenital melanocytic nevus have not been established, the skilled artisan would be unable to evaluate whether a gain of chromosome 10 or 11 alone would predictably type a skin tumor sample as a congenital melanocytic nevus. While one could conduct additional experimentation to determine whether the gain of the entire chromosome 11 or 10 might be associated with congenital melanocytic nevus, the outcome of such research cannot be predicted, and such further research and experimentation are both unpredictable and undue.

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-18 are indefinite over the recitation "gain of chromosome 10, a gain of chromosome 11 or a loss of chromosome 7, or a combination thereof" because it is

unclear whether the gain of chromosomes refers to gains of the whole chromosome and further it is unclear whether a combination thereof is permissive of combinations of whole chromosomes such that partial chromosome analysis is permitted. It is unclear whether the claims are drawn to detecting whole chromosomes or partial chromosomes as indicative of congenital melanocytic nevus.

B) Claims 1-18 are indefinite because it is unclear as to whether the claims are intended to be limited to methods of typing a growth arising in association with a congenital melanocytic nevous or typing a skin tumor sample as being benign. The claims are drawn to a method for typing a growth arising in association with a congenital melanocytic nevus. However, the final process step is one of typing the skin tumor sample as a benign growth. It is noted that a method of typing encompasses all forms of typing growths (e.g., typing a growth as benign, malignant, stage I, stage II etc) and "typing the skin tumor sample as benign" encompasses typing all forms of skin tumors as benign. Accordingly, it is unclear as to whether the claim method is one for a method of typing as a congenital melanocytic nevus or as a benign growth. The claims may be easily amended to recite "congenital melanocytic nevus" in the last step of the claim to overcome this rejection.

C) Claims 1-18 are indefinite over the recitation "a growth arising in association with a congenital melanocytic nevus." It is unclear what is encompassed by a growth arising in association with a congenital melanocytic nevus.

D) Claims 7-8 are indefinite over "the detecting step" because Clam 6 contains two detecting steps. It is unclear which detecting step in particular is being referred to as "the detecting step."

E) Claims 7-8 are indefinite over the recitation "target nucleotide sequence" because "target nucleotide sequence lacks proper antecedent basis. Claim 6, from which Claim 7-8 depend refers to a "target polynucleotide sequence." This rejection may be easily overcome by amending the claims to all refer to a polynuleotide or all refer to a nucleotide.

Conclusion

4. No claims allowable.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

J. Goldberg
Jeanine Goldberg
April 4, 2003

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